

Exhibit G

Amide

PHARMACEUTICAL, INC.

101 EAST MAIN STREET LITTLE FALLS, NJ 07424 USA

ANDA - 40-282

2/21/05

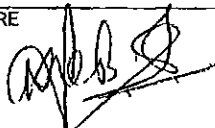
ANNUAL REPORT

1/1/04 - 12/31/04

DIGOXIN TABLETS, USP

0.125 mg and 0.25 mg

AMIDE COPY

TRANSMITTAL OF ANNUAL REPORTS FOR DRUGS FOR HUMAN USE (21 CFR 314.81)		DATE SUBMITTED 2/21/2005	Form Approved: OMB No. 0710-0002 Expiration Date: March 31, 2005 See OMB Statement on Reverse.													
NOTE: This report is required by law (21 USC 355; 21 CFR 314.81). Failure to report can result in withdrawal of approval of the New Drug Application.			1. NDA OR ANDA NUMBER <table border="1" style="width: 100%; text-align: center;"> <tr> <td>N</td> <td>4</td> <td>0</td> <td>2</td> <td>8</td> <td>2</td> </tr> </table>		N	4	0	2	8	2						
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4. APPLICANT AMIDE PHARMACEUTICAL, INC.			PHONE NUMBER (973) 890-1440													
5. DRUG NAME DIGOXIN TABLETS, USP 0.125 mg and 0.25 mg			6. TYPE OF REPORT (Check one) <input checked="" type="checkbox"/> ANNUAL <input type="checkbox"/> OTHER													
7. OTHER NDA/ ANTIBIOTIC APPLICATION NUMBERS (List all numbers if any part of report applies to more than one number.)			3. CFR SECTION NUMBER (Antibiotic only) 8. PERIOD COVERED BY REPORT <table border="1" style="width: 100%; text-align: center;"> <tr> <th colspan="2">FROM</th> <th colspan="2">TO</th> </tr> <tr> <th>YEAR</th> <th>MONTH</th> <th>YEAR</th> <th>MONTH</th> </tr> <tr> <td>2004</td> <td>01</td> <td>2004</td> <td>12</td> </tr> </table>		FROM		TO		YEAR	MONTH	YEAR	MONTH	2004	01	2004	12
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REPORT INFORMATION REQUIRED (See § 314.81 for description) (Enter type of information attached under "Identification." If you have nothing to report, enter None.) (INFORMATION IN "9b" AND "9c" IS ALWAYS REQUIRED.)																
TYPE OF INFORMATION		IDENTIFICATION (Volume No.(s) / Tab(s) / Page(s) of Report)														
a. SUMMARY OF SIGNIFICANT NEW INFORMATION		NONE														
b. DISTRIBUTION DATA		ENCLOSED														
c. LABELING (Whether or not previously submitted)		ENCLOSED														
d. CHEMISTRY MANUFACTURING AND CONTROLS CHANGES <input checked="" type="checkbox"/> SUPAC		Extension of expiration period to 3 years based on 3 batch room temperature data. Attachment 4.														
e. NONCLINICAL LABORATORY STUDIES		NONE														
f. CLINICAL DATA		NONE														
g. STATUS REPORT POST-MARKETING STUDIES		NONE														
h. STATUS OF OPEN REGULATORY BUSINESS (Optional)		NONE														
TYPED NAME AND TITLE OF RESPONSIBLE OFFICIAL OR AGENT JASMINE SHAH, M.S., R.Ph. DIRECTOR, REGULATORY AFFAIRS		FDA USE ONLY														
SIGNATURE 		10. NDA OR ANDA NUMBER <table border="1" style="width: 100%; text-align: center;"> <tr> <td>N</td> <td>4</td> <td>0</td> <td>2</td> <td>8</td> <td>2</td> </tr> </table>			N	4	0	2	8	2						
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11. DATE OF RECEIPT <div style="text-align: center; font-size: 1.2em;"> RECEIVED FEB 22 2005 OGD / CDER </div>																
APPLICANTS RETURN ADDRESS (Type within the window envelope tic marks) JASMINE SHAH AMIDE PHARMACEUTICAL INC. 101 EAST MAIN STREET, LITTLE FALL, NJ 07242																

Amide
PHARMACEUTICAL, INC.

101 East Main Street
Little Falls, New Jersey 07424

Telephone (973) 890-1440
Fax (973) 890-7980

February 21, 2005

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research
Metropark North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773.

Re: Annual Reporting of ANDA 40-282
Digoxin Tablets, USP 0.125 mg and 0.25 mg

Dear Mr. Buehler:

In reference to the submission of "Transmittal of Periodic Reports for Drugs for Human Use" for Digoxin Tablets, USP 0.125 mg and 0.25 mg, enclosed please find form FDA 2252 (Attachment 1) and the necessary documents. This report covers period from January 1, 2004 to December 31, 2004.

COMPLAINTS: A total of nineteen (19) complaints were received for these products during the reporting period. Enclosed please find a complaint summary (Attachment 2).

STABILITY: Pertinent room temperature stability data for the following batches tested during the reporting period is enclosed (Attachment 3):

Digoxin Tablets, USP 0.125 mg

100's (metal cap) - 1095A
5000's (metal cap) - 1095A

100's (plastic cap) - 1290A, 1291A, 1292A, 2319A1, 3463A1, 4076A
5000's (plastic cap) - 1290A1, 1291A1, 1292A, 2319A, 3463A, 4076A1

Digoxin Tablets, USP 0.25 mg

100's (metal cap)- 1108A
5000's (metal cap)- 1108A

100's (plastic cap)- 1288A1, 1331A, 1332A, 2331A, 3490A1
5000's (plastic cap)- 1288A, 1331A1, 1332A1, 2331A1, 3490A

HIGH QUALITY PHARMACEUTICALS

Page 3 of 4
February 21, 2005
Annual Reporting of ANDA 40-282
Digoxin Tablets, USP 0.125 mg and 0.25 mg

FD&C Green Lake Blend LB-603: Raw material analytical method was revised on March 15, 2004 to change Identification test as per FDA color additive certification method. Enclosed please find revised copy of method and specifications for FD&C Green Lake Blend LB-603 (Attachment 7).

There were no changes in the analytical methods from that submitted earlier.

MANUFACTURING AND CONTROL CHANGES:

There were no changes made in manufacturing and control procedures for these products during reporting period.

Digoxin Tablets, USP 0.125 mg

A total of forty two (42) batches of Digoxin Tablets, USP 0.125 mg were manufactured during the reporting period. Batch #'s 4076A, 4077A, 4151A, 4152A, 4153A, 4154A, 4155A, 4232A, 4234A, 4235A, 4236A, 4237A, 4275A, 4276A, 4277A, 4278A, 4279A, 4366A, 4367A, 4368A, 4369A, 4370A, 4412A, 4413A, 4414A, 4440A, 4441A, 4442A, 4443A, 4444A, 4606A, 4607A, 4610A, 4611A, 4612A, 4637A, 4638A, 4639A, 4640A, 4641A, 4661A, and 4662A were 4,800,000 tablets batch size each. Equipment comparable to the submission batch was used to manufacture these batches.

Digoxin Tablets, USP 0.25 mg

A total of thirty six (36) batches of Digoxin Tablets, USP 0.25 mg were manufactured during the reporting period. Batch #'s 4183A, 4184A, 4185A, 4186A, 4187A, 4301A, 4302A, 4303A, 4304A, 4305A, 4325A, 4331A, 4333A, 4334A, 4335A, 4336A, 4451A, 4452A, 4453A, 4454A, 4486A, 4487A, 4488A, 4489A, 4490A, 4582A, 4692A, 4693A, 4694A, 4695A, 4696A, 4731A, 4732A, 4733A, 4734A, and 4735A were 4,200,000 tablets batch size each. Equipment comparable to the submission batch was used to manufacture these batches.

PACKAGING AND DISTRIBUTION CONTROLS:

A CBE-30 supplement for alternate packaging and labeling site was submitted on November 4th, 2004 and approved on January 13th, 2005.

There were no other changes made in packaging and distribution controls for these products during the reporting period.

NOTE: This report is required by law (21 USC 355; 21 CFR 314.81). Failure to report can result in withdrawal of approval of the New Drug Application.

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AMIDE PHARMACEUTICAL, INC.

PHONE NUMBER
(973) 890-1440

5. DRUG NAME
DIGOXIN TABLETS, USP 0.125 mg and 0.25 mg

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N	4	0	2	8	2
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2. Report No. (FDA Complete)

Y-					
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APPLICANT NOTE

Reference NDA and Y numbers
(entered on Acknowledgement Copy) in any
subsequent correspondence regarding report.

3. CFR SECTION NUMBER (Antibiotic only)

6. TYPE OF REPORT (Check one)

☒ ANNUAL ☐ OTHER

8. PERIOD COVERED BY REPORT

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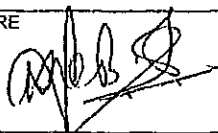
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TYPED NAME AND TITLE OF RESPONSIBLE OFFICIAL OR AGENT
JASMINE SHAH, M.S., R.Ph.
DIRECTOR, REGULATORY AFFAIRS

SIGNATURE



APPLICANTS RETURN ADDRESS (Type within the window envelope t/c marks)

JASMINE SHAH
AMIDE PHARMACEUTICAL INC.
101 EAST MAIN STREET, LITTLE FALL, NJ 07242

FDA USE ONLY

10. NDA OR ANDA NUMBER

N					
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11. DATE OF RECEIPT

Digoxin Tablets, USP 0.125 and 0.25 mg
Complaint Summary 1/1/2004 to 12/31/2004

A total of nineteen (19) complaints were received during January 2004 to December 2004 reporting period. The complaints received, were noted as:

COMPLAINT	COMPLAINT SUMMARY
1. Dizziness	Known adverse effect
2. Fatigue, dizziness, diarrhea	Known adverse effects
3. Increased blood pressure	Known adverse effect
4. Nausea	Known adverse effect
5. Contamination	Metal object seen in tablet
6. Thick tablet	Tablet was left in the vibrator during the set up of the machine and passed undetected.
7. Dispensing Error	Dispensing error by pharmacist
8. Weight Loss	Unknown adverse effect
9. Hair loss	Unknown adverse effect
10. Black deposits on teeth	Unknown adverse effect
11. Fast dissolution of the tablets	Incorrect administration of the product
12. Hypophosphatemia and leucopenia	Patient was receiving multiple medications and was enrolled on new drug investigational study. Patient might experience drug interaction effect.
13. Products mix-up	Dispensing error by pharmacist
14. Short count (30 tablets short)	One month supply was dispensed before
15. Nausea	Known adverse effect
16. Products mix-up	Dispensing error by pharmacist
17. Palpitation	Known adverse effect
18. Blurred vision	Known adverse effect
19. Short Count (empty bottle)	Isolated incident. Extremely rare case